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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the

BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of Gerhard J. Haas

Serial No. 10/046,897

Filed: Jan. 17, 2002

Appeal No.

Art Unit 1651

Examiner Susan D. Coe

For: Hop-Based Udder and Teat Dips and Washes

APPELLANT'S REPLY BRIEF

Appellant, Gerhard J. Haas, respectfully submits this Reply Brief in response to the Examiner's Answer to Appellant's Brief, which answer was mailed on April 17, 2005.

In essence, the Examiner's Answer is an affirmation of her rejections on the art throughout the prosecution of the subject application. She agrees that the Japanese Application Serial No. 01172332 A (JP '332) does not disclose washing or dipping the udders and teats of cattle in a hops solution as called for by the claims, yet somehow finds that JP '332 provides the equivalent of such a disclosure. Further, she picks and chooses from the disclose of that application in a way that would be completely non-obvious to one of skill in the art; the latest count is 1 in 228 variations. Finally, she disregards disclosures

¹ In commenting on the claims on appeal, the Examiner does correctly note that the word "humulone" was omitted from the end of claim 4. The Examiner is thanked for calling attention to this inadvertent omission.

in in JP '332 that teach directly away from her interpretation of that reference.

I. The Certified Translation of JP '332 Governs.

JP '332 was translated by Dr. Takeo Ohashi, president of Ohashi High
Technology Corporation and a Ph.D. who is proficient in both the Japanese and English
languages. See Dr. Ohashi's Translation Certificate. Dr. Ohashi certified that the
translated paragraph in issue is as follows:

"The method of giving it is either oral or non-oral administration. As non-oral administration, intramuscular, intra stomach, transdermal, nasal and vein administration can be used."

When asked to further define the Japanese word that he translated as "transdermal," Dr. Ohashi noted:

"The word, transdermal, is used interchangeably with transcutaneous. It means 'through the skin.' Examples of transdermal administration would be by syringe injection or the use of a medicated patch."

Fixating on the word, transdermal, the Examiner has apparently decided that Dr. Ohashi is incorrect in his translation from the Japanese. According to the Examiner the Japanese word that was translated as "transdermal" or "transcutaneous" must cover washing or dipping. Thus, she says:

"The reference as translated states that the hops extract can be applied transdermally <u>or to the skin</u>...." [Answer, p. 9, lines 17, 18] Of course it does not state that the extract can be applied to the skin. Where does it make that disclosure? She goes on:

"In addition, a person of any degree of skill in the pharmaceutical art would appreciate that syringe injection is not transdermal administration." [Ibid. line 21] So, the

Examiner directly contradicts the translator.... without showing that she has any proficiency in the Japanese language. She also says:

"Syringe injection pierces the skin; thus, it is not administration through the skin. Thus, the appellants conjecture regarding the teaching of the reference to administer by injection or medicated patch is outside any suggestion of the reference's teaching of transdermal administration." [Answer, page 7, lines 1 to 4]

"However, washing and dipping is well within the scope of transdermal administration." [Ibid. lines 16 and 17]

With all respect, the Examiner's line of reasoning is the essence of illogic.

There is a Japanese word, whatever it is. What does it mean in English? There may be no precise English counterpart, but the translator effectively says, "The closest I can come is transdermal or transcutaneous. One example of that form of application is syringe injection."

What the Examiner is doing is treating the Japanese application as though it were written in English and used the word, transdermal. Then she argues that transdermal does not include syringe injection, but does include washing. What is at issue is the meaning of the Japanese word that was translated. Whatever that word would translate to in English --and there may be no precise counterpart-- it includes syringe injection. For the Examiner to say it does not is for the Examiner to tell the translator that he is wrong without the slightest proof of her proficiency in the Japanese language. Whatever the Japanese word means, it includes syringe injection according to Dr. Takeo Ohashi, and for the Examiner, without substantiation, to say it does not evidences a serious misunderstanding of the reference application.

2. What the Examiner Has Done is the Essence of Picking and Choosing.

With appropriate citations, in Appellant's opening brief it was pointed out that it is the reference as a whole that must be considered and that an Examiner should not pick and choose those parts that support a position while disregarding those parts that do not. In response, at page 8, line 12 of the Answer the Examiner says she is not being overly selective because she has chosen one word, transdermal, from six possibilities. Once again this is submitted to be an example of failing to regard the reference as a whole.

JP '332, the Japanese "art-blocker" application, discloses 19 separate and distinct genera all of which are alleged to have some efficacy in the treatment of bovine mastitis. The Examiner has chosen one genus, hops. Then the reference says that administration can be oral or non-oral, and non-oral is chosen. Finally, the Examiner selects a single one of six non-oral means, and fixates on one Japanese word, whose English translation uses as an example, syringe injection. It appears that the possible variants are 19 times 2 times 6, or 228 different combinations that are available, and the Examiner has chosen 1 of the 228 variants disclosed. That, it is submitted, is exemplary of improperly picking and choosing from elements in a disclosure.

3. The Examiner Has Disregarded Those Parts of JP '332 That Teach Away from the Claimed Invention.

At pages 5 and 6 of his opening brief, applicant asked the Board to look at page 14 of the translation, attached to that brief, and to this, as Exhibit A. That page includes a paragraph which says that the amount of galenical to be administered is dependent on the body weight of the animal being treated. Obviously that paragraph teaches away from washing or dipping a cow, where the concentration of the hop solution

would have nothing to do with the body weight of the cow. Small cow or large cow, the effective concentration of the solution would be the same.

Applicant is not certain whether the Examiner has responded to this clear teaching of JP '332 away from the claimed invention. She may be saying that this disclosure only relates to the amount of galenical put in the animal's feed. Not so. It can apply as well to the other non-oral means of administration: intramuscular, intra stomach...and syringe injection.

Further, another part of the disclosure of JP'332 expressly disputes the Examiner's contention, without proof, that the Japanese word translated as "transdermal" means application to the skin rather than through the skin. It is found on the same page, Exhibit A, where the antepenultimate paragraph reads:

"Moreover, there is no need to be concerned over the adverse effects of residual agents on the human body, and therefore it is appropriate to administer the agents to cows for meat consumption to prevent and treat bovine mastitis caused by staphylococci."

Residual agents would refer to what is left over or remains after the treatment of the cow, such as the residue from washing or dipping the udders of a cow in the galenical. JP'332 expressly says that one of the advantages of its treatment is that there is no such residue. So, once again, it teaches away from any interpretation of its disclosure as including a washing or dipping step, which would certainly leave a residue.

Because JP'332 expressly teaches away from any washing or dipping step, it cannot be said to disclose any such treatment, even if the Examiner had submitted proof of her translation of the Japanese word in issue, which has not been done. And because of such teaching away, there is surely no motivation to modify the reference to move toward a

washing or dipping step; indeed, the motivation would be to avoid any such step.

4. As JP'332 Does Not Teach Washing or Dipping, No Combination of References Meets the Terms of the Claims.

Regarding the combination of U.S. Patent No. 5,370,863 and JP'332, the Examiner says that the U.S. patent, which uses a hop compound in a deodorant, teaches "topical application" of a hop compound, and that this would somehow motivate one of skill to topically apply a hop compound to a cow. However, it is respectfully submitted that the only topical application it would motivate in the case of a cow would not be topical application in general, but use as a deodorant, because US'863 does not teach topical application of a hop compound in general, such as in a bath or shower, but a specific application: as a deodorant.²

A fortiori, U.S. Patent No. 5,370,863 does not fill the gap, disclosing as it does the use of hop compounds in dentifrices. Why the use of hops in a dentifrice would motivate one to use it to wash the udders of cows simply does not follow.

5. Conclusion Regarding Patentability.

Applicant repeats that the disclosure of JP'332 is basic to the all of the rejections of record. Does it disclose washing the udders of cows with a hops solution, which it manifestly does not, or would it would motivate one of skill in the art to do so, which is the Examiner's position? It is respectfully submitted that the Examiner has presented no logical basis for the mutation of JP'332's disclosure of "through the skin" administration, such as by syringe injection, to "to the skin," such as by washing or dipping, as that has

² This type of reasoning could eliminate the non-obviousness of any invention. While admittedly somewhat of a hyperbole, one might say that a wagon is a means of transportation. Birds fly. So, the combination makes an airplane obvious. The error in logic is expanding the wagon or deodorant usage to "means of transportation" or "topical application."

not been shown to be a proper translation and as the reference as a whole teaches away from washing udders on at least two occasions. What the Examiner has done is take a single word from the disclosure of 228 combinations in an obscure Japanese patent application and make it the basis for rejecting an invention that has real, practical value. Based on the citations set forth more fully in applicant's opening brief, such is believed improper as a matter of law. See, e.g., Bausch & Lomb, Inc. v. Barnes/Hind, 706 F.2d 443

WHEREFORE, applicant respectfully requests that the decision of the Primary Examiner finally rejecting claims 1 to 8 of the application on appeal be reversed.

Respectfully submitted,

Dated: May 9, 2005

(Fed. Cir. 1986).

Walter D. Ames, Reg. No. 17,913 Attorney for Appellant

Walter D. Ames, Esq.. 6718 Wemberly Way McLean, VA 22101

Tel: (703) 356-1737 Fax: (703) 448-3055 solvents to leave. The residues are employed as effective fractions, in other words effective constituents. These effective fractions are different from the effective fractions which are previously described in physical and chemical properties and the constituents which can be detected are also different.

The amount to be administered varies in a range from 0.001 mg/body weight kg/day ~ 100 g/body weight kg/day in the original weight of galenicals. An amount of an agent for prevention is different from that of the agent for treatment, and generally the amount to be administered is larger for the latter.

The method of giving it is either oral or non-oral administration. As non-oral administration, intramuscular, intra stomach, transdermal, nasal and vein administration can be used.

[Advantages of the Invention]

As stated above in detail, the present invention provides effective agents and methods to prevent and treat bovine mastitis caused by staphylococci.

The prevention and treatment agents according to the present invention employ galenicals or extracts derived therefrom as the major agent constituents. Thus, there is no problem at all, such as appearance of resistant bacteria and side effects, which are issues with antibiotics. The agents can be administered without concerns.

Moreover, there is no need to be concerned over the adverse effects of residual agents on the human body, and therefore it is appropriate to administer the agents to cows for meat consumption to prevent and treat bovine mastitis caused by staphylococci.

Furthermore, the same disease can be prevented and treated at much cheaper costs than those when antibiotics and so forth are employed.

Further explanation of the present invention is offered below using Test Examples and Examples.



CERTIFICATE OF MAILING

It is hereby certified that on the 9th day of May, 2005 the foregoing Appellant's Reply Brief mailed to the U.S. Patent and Trademark Office by depositing an original and two copies of the Brief in the U.S. mails by first-class, postage-prepaid mail addressed as follows:

Mail Stop Technology Center 1600 Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Walter D. Ames, Reg. No. 17,913

Attorney for Applicant